General

Guideline Title

Acute pain assessment and opioid prescribing protocol. Health care protocol.

Bibliographic Source(s)

Thorson D, Biewen P, Bonte B, Epstein H, Haake B, Hansen C, Hooten M, Hora J, Johnson C, Keeling F, Kokayeff A, Krebs E, Myers C, Nelson B, Noonan MP, Reznikoff C, Thiel M, Trujillo A, Van Pelt S, Wainio J. Acute pain assessment and opioid prescribing protocol. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2014 Jan. 44 p. [76 references]

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. This document is in transition to the GRADE methodology. Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available systematic reviews in literature searches.
- All new literature considered by the work group for this revision has been assessed using GRADE methodology.

The recommendations for acute pain assessment and opioid prescribing protocol are presented in the form of two algorithms with 15 components, accompanied by detailed annotations. Algorithms are provided in the original guideline document at the ICSI Web site for Acute Pain Assessment and Opioid Prescribing (Main algorithm) and Risk Assessment and Treatment. Selected annotations (numbered to correspond with the algorithm) follow.

Quality of evidence (Low Quality, Moderate Quality, High Quality, Meta-analysis, Systematic Review, Decision Analysis, Cost-Effectiveness Analysis, Guideline, and Reference) ratings are defined at the end of the "Major Recommendations" field.

Main Algorithm Annotations

2. Brief Pain Assessment
   In the emergency setting, the work group recommends judicious use of opioids to alleviate pain when it overwhelms the patient's ability to contribute to the assessment process.

3. Comprehensive Pain Assessment
   All patients have the right to an adequate assessment that includes general history and physical, etiology and nature of the pain, appropriate diagnostics, evaluation and treatment for acute conditions. This assessment is important in identifying the onset and progression of the pain and may help focus diagnosis and treatment of the source of the pain. Document pain location, intensity and quality of the patient's pain, and the patient's pain score.

   Past literature identifies that while pain screening, using a numeric pain scale, or developing pain management standards within an organization increases the rate of pain assessments used, it doesn't seem to affect treatment prescriptions or levels of pain *[Low Quality Evidence]*.

   A numeric pain scale to assess patient perception of pain can be valuable as a measure of pain improvement over time, but responding to the pain score by merely prescribing opioids is problematic. Pain perception is multifactorial, and the clinician should obtain additional contextual information from the patient regarding his or her experience and limitations with the pain, as well as psychosocial issues potentially impacting the pain experience.

   An editorial from the American Academy of Pain Medicine suggests that analgesia is often equated with administering more opioid, rather than careful individualized assessment, planning and multimodal treatment approaches *[Low Quality Evidence]*. Responding to a pain score with aggressive opioid treatment may not be safe and therefore not in the patient's best interest *[Low Quality Evidence]*.

   Appropriate Diagnostics

   While the use of diagnostics for evaluation and treatment may be useful, it is important to remember that the identification of pathology on diagnostic tests does not necessarily prove that the identified pathology is causing the patient's pain. Therefore, it is important to complete appropriate diagnostics and use evidence-based guidelines when possible.

   Medication History, Including Past and Current Opioid Use

   Because it is problematic for clinicians to accurately assess a patient's past opioid prescription history, querying a prescription monitoring program (PMP) is recommended. Use of the PMP offers a clinician an opportunity to identify concerns about prescription opioids if the patient is a poor historian or is not forthcoming.

5. Symptomatic Management of Non-Traumatic Tooth Pain
   Many patients experiencing tooth pain may use the emergency department as a source for pain relief if dental insurance is not available or if it is an issue to obtain access to care, such as weekend coverage or after-hours emergency. Due to these potential situations, the Minnesota Dental Association (MDA) developed a position statement in regards to opioid use in non-traumatic tooth pain from which this annotation was derived:

   - Prior to diagnosis and treatment plan for underlying source of pain, use appropriate non-opioid medications for pain management, such as:
     1. Long-acting local anesthetic (i.e., Marcaine for up to eight hours)
     2. Prescription analgesics – non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, which can be very effective for tooth pain
     3. Prescription combination analgesics – ibuprofen in combination with acetaminophen *[Meta-analysis]*, *[High Quality Evidence]*, *[Low Quality Evidence]*
     4. Topical anesthetic rinse when indicated or upon presence of stomatitis, mucositis or mouth ulcers

5. Antibiotics with the presence of swelling or exudates in the cheek, jaw or gum tissue
6. Chlorhexidine antimicrobial mouth rinse when indicated, to help with localized gum inflammation and infection, as well as soothe gum tissue

- Do not prescribe opioids without an examination and diagnosis of the underlying reason for the tooth pain by a dental provider as soon as possible. Opioids can mask pain and allow the patient to ignore a potential underlying serious dental problem, such as an abscess.
- Diagnosis should include appropriate tests and x-rays.
- Refer to a dental provider and assist with access to follow-up when possible.

Collaboration is needed between the medical and dental community to help patients access a dental provider who can then diagnose and create an appropriate treatment plan, which would not typically necessitate the use of opioid medications. When deemed absolutely necessary, the dental provider could prescribe an opioid medication, but only after an examination and diagnosis of the dental complaint.

Referral and Treatment Strategies for the Medical Community

- Recognize local and systemic diseases that present as tooth pain requiring treatment by a medical clinician (such as herpes zoster, trigeminal neuralgia, osteonecrosis, etc.)
- Evaluate medical history and any concerns that may affect having a dental treatment referral.
- Actively use a prescription monitoring program and convey any concerns to the dental provider.
- Determine the patient's intent to seek dental care. Follow-up should be as soon as possible, as dental infection or abscess can progress rapidly.
- Maintain an updated list of dental providers in the area, and assist the patient, if needed, to access a dental provider.

8. Acute Exacerbation of Existing Chronic Pain
    - Consult the patient's pain care plan prior to prescribing any medications.
    - Refer to the NGC summary of the ICSI guideline Assessment and management of chronic pain.
    - Consider collaborating with the clinician managing the patient's chronic pain care plan, an interdisciplinary team or available resources to provide appropriate chronic pain management.
    - Check PMP for history of opioid prescriptions.

It is important to identify the source of pain rather than just treating for acute pain, since treatment for the chronic pain patient can be significantly different. If at all possible, review the patient's pain plan, confer with the clinician managing the patient's chronic pain, or consult with a pain specialist about other options that would promote relief without complicating the current medication and/or therapy prescribed for the patient. Include supportive family and/or caregivers, as identified by the patient, in shared decision-making.

Because of potential risks and adverse effects, clinicians are encouraged to avoid prescribing increased dosage or additional opioids. Assess the patient's mental health status and social situation to determine if additional resources (e.g., social services, behavioral health, pain management or addiction medicine consult) may be appropriate.

Opioid use disorder (i.e., heroin or pharmaceutical opioid addiction) makes management of pain with opioids highly problematic. Additional opioid prescriptions should be avoided in patients actively addicted to opioids, if at all possible. These patients should be referred to appropriate addiction treatment, including a methadone maintenance clinic or a buprenorphine clinician. Patients enrolled and in good standing at a methadone maintenance clinic for opioid use disorder, (including heroin) can be treated for acute pain with normal opioid dosing (i.e., doses used for opioid-naive patients). It is recommended to obtain a release of information to coordinate care with the patient's methadone maintenance clinic. Buprenorphine-containing products such as Suboxone typically indicate that the patient has an opioid use disorder and is in treatment. Naltrexone, an opioid receptor antagonist, is indicated for the treatment of both alcohol and opioid use disorders. Recent buprenorphine or naltrexone use will block the analgesic effects of opioids and could precipitate opioid withdrawal. Thus, when treating a patient on buprenorphine or naltrexone who has a strong indication for opioids, it is wise to consult the patient's addiction specialist to manage the interactions of the patient's medications. The addiction clinician will require a release of information for this communication *[Guideline]*.

Opioid Withdrawal Presenting as Acute Pain

Consider opioid withdrawal when evaluating opioid-tolerant patients who present with acute pain complaints or gastrointestinal symptoms. Opioid withdrawal can occur when patients stop their medications, have an opioid use disorder (e.g., heroin addiction) or have lost or overused their medications. Patients are often reluctant to share this information with their clinician. Opioid withdrawal presents with anxiety 12 hours after the last dose and becomes physically detectable 24 hours after the last use of short-acting opioids. Withdrawal from long-acting opioids becomes physically detectable at 48 hours after last use. In a given patient, the manifestation of opioid withdrawal is individual. Opioid addicts should not be given opioids for treatment of withdrawal but rather referred to a treatment or detox center, per

direction from the U.S. Drug Enforcement Administration (DEA) Diversion Program: http://www.justice.gov/dea/ops/diversion.shtml . Unless the patient is otherwise medically unstable, withdrawal is not life threatening, although it may be very distressing. Reassurance and comfort measures are appropriate treatments *[Low Quality Evidence]*.

9. New Diagnosis Unrelated to Chronic Pain
    - Consult the patient's care plan or prescribing clinician prior to prescribing any additional medications.
    - Consider collaborating with the clinician managing the patient's chronic pain care plan, an interdisciplinary team or available resources to provide appropriate pain management.
    - Consider monitoring in an appropriate care setting if the patient's condition warrants additional opioids.
    - For optimal safety, avoid prescribing long-acting and/or higher dosages in patients chronically on opioids.

    Often, patients receiving chronic opioids have a pain management care plan, and this plan should be consulted prior to prescribing opioids for acute pain. The work group agreed that due to a lack of evidence, the safest course in an unmonitored outpatient setting is to treat acute pain in the opioid-using patient with the same dose and number of pills as in the opioid naïve patient.

    Dosing opioids for acute pain in a patient already on opioids is problematic. The patient may require a higher dose to achieve the same analgesic effect. The higher dose puts the patient at greater risk for an adverse event. Predicting the safe additional opioid dose in such a patient is complex and dependent on variables that are unique to the patient and difficult to predict. Many such patients will achieve adequate analgesia from normal dosing of opioids. Patients chronically on opioids do not require a longer than normal course of treatment for acute pain.

    If the clinician is concerned about the patient's risk factors and feels that the patient would benefit from carefully managed opioids, active monitoring is an appropriate care setting to ensure safety would be warranted.

Risk Assessment and Treatment Algorithm Annotations

10. Is Non-Opioid Treatment or Therapy Most Appropriate?
    Opioids are not as effective in non-cancer pain management as once believed *[Guideline]*. While pain management with opioids has been prevalent and promoted historically, recent studies have demonstrated that opioids are being used inappropriately, thus leading to misuse, abuse, dependence, overdose and diversion.

    Opioids actually change the chemistry of the brain and its response to pain.

    - Homeostatic adaptations within the central nervous system (CNS) to opioid exposure may contribute to the development of tolerance *[Low Quality Evidence]*.
    - Opioids profoundly influence the synaptic plasticity that underlies learning and memory, leading to the potential development of addiction *[Low Quality Evidence]*.
    - Opioids may lead to an enhanced pleasurable effect *[Low Quality Evidence]*.
    - Opioids may cause increased neuropathic pain *[Low Quality Evidence]*.
    - Opioids suppress the release of noradrenaline, causing drowsiness, reduced respirations and lower blood pressure *[Low Quality Evidence]*.
    - Opioids lead to the release of excitatory neuropeptides that cause peripheral nociceptive stimulation *[Low Quality Evidence]*.
    - Opioid-induced hyperalgesia (OIH), defined as a state of nociceptive sensitization caused by exposure to opioids, may develop, resulting in increased sensitization to painful stimuli *[Low Quality Evidence]*.

    This may clinically manifest as apparent opioid tolerance, worsening pain despite accelerating opioid doses or abnormal pain symptoms such as allodynia *[Guideline], [Low Quality Evidence]*.

    Additional Opioid Adverse Effects

    - Gastrointestinal effects *[Guideline]*
        - Constipation
        - Anorexia
        - Bloating
        - Nausea/vomiting
        - Abdominal cramping
    - Respiratory effects *[Low Quality Evidence]*
        - Decreased central drive
        - Suppressed gag reflex

    - Reduced frequency of respirations
    - Altered normal breathing rhythm
    - Inhibition of brain stem arousal centers
    - Blunted response to hypoxia and hypercapnia
- Effects on sleep *[Low Quality Evidence]*
    - Increased percentage of time spent in light sleep
    - Decreased percentage of time spent in deep sleep
- Bladder effects *[Low Quality Evidence]*
    - Decreased detrusor muscle tone and force of contraction
    - Decreased sensation of fullness and urge to void
    - Inhibition of voiding reflex
- Immunologic effects *[Low Quality Evidence]*
    - Diminished cellular immune responses, natural killer cell activity, cytokine expression and phagocytic activity
- Endocrine effects *[Guideline]*
    - Inhibition of adrenocorticotropic hormone (ACTH) and cortisol secretion, causing a decreased glucocorticoid response
    - Inhibition of luteinizing hormone (LH)- and gonadotropin-releasing hormone secretion, resulting in lower steroid hormone levels
    - Inhibition of estradiol and testosterone secretion, resulting in hypogonadism, menstrual irregularities, sexual dysfunction, infertility and osteoporosis
    - Inhibition of insulin secretion, leading to hyperglycemia and worsening diabetes
    - The patient should be provided with all the information regarding options, risks and benefits of treatment. Family and/or caregivers may also be included as patient indicates.

11. Appropriate Therapy and/or Referral
    - Treat with other analgesics or NSAIDs, physical, psychological, interventional, or other appropriate non-opioid therapies.
      Non-opioid analgesics for pain and/or therapies that would support pain relief, improved function or healing should be the first consideration. Some types of pain would be better managed with alternative medications, such as gabapentin for neuropathy or calcitonin for bone pain associated with osteoporosis. However, NSAIDs and other anti-inflammatories are not without their limitations and side effects. For some conditions, they may prevent healing and should be prescribed judiciously *[Low Quality Evidence]*. Provide risks and benefits of all options for the patient to guide discussion and support shared decision-making.

      Identification of appropriate treatment must also include evaluation of activities of daily living (ADLs), work situation and psychosocial needs. If available, include in the discussion supportive family members and/or caregivers as identified by the patient. Document treatment recommendations in the patient's plan of care, and provide this information to the clinician who will be providing follow-up care.

      For additional information on evidence-based treatment modalities for pain, see the NGC summary of the ICSI guideline Assessment and management of chronic pain.

    - Reassure and provide patient education, including expected duration of pain episode and warning signs that would require immediate medical attention.
      With many acute pain situations, the clinician can help the patient anticipate the endpoint for pain. For instance, viral infections have an endpoint, and a broken bone has a point where the pain should be subsiding. It is important to share the information so the patient knows what to expect.

      If the pain does not appropriately improve in the expected time frame, patients should follow up with their primary care physician for reassessment and referral to a behavioral health or pain specialist as needed.

12. Complete the ABCDPQRS Opioid Risk Assessment
    The mnemonic ABCDPQRS provides a simple way to remember contraindications to opioids.

    Alcohol Use

    Alcohol affects judgment and memory, and impairs respiration when combined with opioids, all of which place the patient at increased risk of accidental overdose and trauma. There is no known safe dose of alcohol for a patient on opioids, particularly when the patient is opioid naive or on a higher dose than previously taken. The safest recommendation for patients on new or higher-than-baseline doses of opioids is to abstain from alcohol completely.

In a patient using opioids for pain, an alcohol use disorder confers particular risk when combining alcohol and opioids in an unsafe manner or using opioids inappropriately even in the absence of alcohol use.

Refer to the original guideline document for information on screening tools and the Screening, Brief Intervention, and Referral to Treatment (SBIRT) model for substance abuse.

Benzodiazepines and Other Drug Use

Like alcohol, benzodiazepine (BZD) used concurrently with opioids increases the risk of oversedation, overdose and trauma. Patients using BZDs and opioids should be counseled not to combine these medications. The BZD prescriber should be made aware of opioid prescriptions if possible. Patients on opioids and BZDs and with other risks factors for opioid-related adverse events (respiratory compromise, risk of falls, or substance use disorder) are at a particularly increased risk of harm *[Guideline]*.

Marijuana use is so pervasive that it is not practical to test every patient in acute pain for marijuana. But those patients known to consume it regularly warrant more careful monitoring when prescribing opioids for pain *[Low Quality Evidence]*.

Cocaine use has been associated with increased risk of diversion of opioids, and any patient with a substance use disorder should be educated carefully about the risks of combining drugs and overusing opioids. Clinicians may choose to prescribe fewer pills, use smaller doses and follow up within three to five days *[Low Quality Evidence]*, *[Meta-analysis]*.

Further information on substance use issues can be accessed at http://www.samhsa.gov/data/nsduh/2k11results/nsduhresults2011.htm .

Also see Appendix C, "DSM-V Substance Use Disorder Criteria," in the original guideline document.

Clearance and Metabolism of the Drug

Many opioids require renal clearance of active metabolites. Morphine and meperidine are toxic in renal insufficiency (glomerular filtration rate [GFR] <60). For patients with severely decreased renal function (GFR <30), hydrocodone and oxycodone will have delayed elimination. Before prescribing opioids, consider whether the patient may be at risk of renal insufficiency, and check the medical record for a recent serum creatinine.

Hepatic impairment, if severe, can affect the metabolism of many opioids. A dosage adjustment or change of dosing interval may be necessary for morphine, hydrocodone and oxycodone. For patients with impaired liver function, consider lowering the dose of acetaminophen or, preferably, avoiding the use of acetaminophen/opioid combination medication altogether. Half of the liver transplants in America are caused by acetaminophen-related liver failure; and half of those are caused by combination opioid/acetaminophen product overuse. Before prescribing a combination product, evaluate the patient for possible liver impairment. If acetaminophen is not needed, do not prescribe the combination product *[Low Quality Evidence]*.

Delirium, Dementia and Falls Risk

Patients on acute dosing of opioids are at an increased risk from falls and other accidental trauma. This is particularly so for geriatric patients. Opioids should be used cautiously for patients with past falls or at an increased risk of fracture. Some guidelines suggest prescribing half the normal initial dose when treating the elderly. Other CNS depressants such as anticholinergic medications, alpha adrenergic blockers and benzodiazepines will compound the risk of falls and fractures in patients on opioids.

Opioids can precipitate delirium in some patients. Those with significant risk factors for opioid-induced delirium include the elderly; patients with cognitive impairments, polypharmacy, advanced liver or kidney disease; and patients with prior episodes of delirium precipitated by opioids. Consider these factors when dosing opioids, and educate the patient and his/her family of the risks *[Guideline]*.

Psychiatric Comorbidities

Opioids should be regarded as having powerful anxiolytic properties as well as analgesic properties. Opioids have no indication for mental health disorders, yet this anxiolytic effect is readily recognizable by the distressed patient. Psychic distress may exacerbate nociceptive (physical) pain or be confused for physical pain. The most common reason for illicit opioid use in high school is for relief of anxiety. Many mental health disorders are correlated with increased opioid misuse, opioid related accidents and accidental opioid overdose death. Post-traumatic stress disorder and childhood sexual trauma increase the risk of opioid-related adverse events tenfold. Depression and anxiety disorders (including generalized anxiety disorder, social anxiety disorder and obsessive compulsive disorder) are known to increase the risk of opioid misuse and harm, as well. Childhood attention deficit hyperactivity disorder is a risk for later pharmaceutical misuse. Opioid withdrawal can exacerbate psychotic symptoms *[Low Quality Evidence]*.

A mental health condition does not preclude opioid use for pain. But doctors prescribing opioids for pain should carefully consider if the pain reported is a surrogate for psychic distress. Patients with mental health disorders should be educated that they will experience psychic relief from the opioids – and that this relief is not the intended effect of the pain medication. Patients with untreated or undertreated mental health disorders should be offered safe and appropriate psychiatric care. Before prescribing opioids to mentally ill patients, an assessment of suicide risk is wise. The Safe-T tool is recommended by the American Psychiatric Association practice guidelines and can be found at http://www.integration.samhsa.gov/images/res/SAFE_T.pdf.

Query the Prescription Monitoring Program

Query a PMP when prescribing opioids for an acute pain condition. In greater than 50% of acute pain visits, the patient has already received an opioid for that pain within one month, from a different clinician. The PMP lists all controlled substances filled in the state in the last 12 months and increasingly includes data from other states, as well. (Prescriptions from methadone maintenance clinics, Indian Health Services, long-term care facilities, and the Veterans Administration pharmacy are currently not included in Minnesota.) Non-prescribers (administrative help, nurses, interns) can query the PMP as a physician proxy in Minnesota in order to expedite the process *[Low Quality Evidence]*.

Respiratory Insufficiency and Sleep Apnea

Patients with hypoxia, hypercapnia or conditions or medications that affect their ability to breathe will be at an increased risk of respiratory insufficiency and respiratory arrest from opioids. Common risk factors include sleep apnea, chronic obstructive pulmonary disease, congestive heart failure and concurrent use of benzodiazepines, alcohol or barbiturates. Sleep apnea is a commonly missed diagnosis, and the symptoms of this disease are often not readily apparent to the patient or physician. Opioids likely exacerbate both obstructive and central sleep apnea.

Safe Driving, Work, Storage and Disposal

Minnesota law states that driving under the influence of a controlled substance or having any amount or the metabolites of a Schedule II controlled substance constitutes a DWI. Aside from the legal implications, it is unsafe to drive on new or newly increased doses of opioids, let alone attempting to drive while in acute pain. For this reason, any patient receiving opioids for pain should be instructed not to drive within 24 hours of taking opioids or when having a severe episode of pain. Similarly, work, parenting and other duties requiring concentration and coordination will be impaired by opioids and by acute severe pain itself. Patients in acute pain, especially if receiving opioids, should be instructed to avoid sole parenting duties and work responsibilities until 24 hours from their last dose and when the pain becomes manageable. Involve and inform the patient's family and/or caregiver to provide additional support in the areas above.

Refer to the original guideline document for information on elements of the ABCDPQRS opioid risk assessment.

13. Does Potential Benefit of Opioids Outweigh Potential Risk?
Clinicians should assure the benefit clearly outweighs the risk when prescribing opioids.

The work group recommends that the severity and nature of the injury or illness, and the patient's perception of pain, be weighed carefully against the relative risk of adverse effects and potential harm from the use of opioids. The Risk Benefit Graph provided in the original guideline document is a way to assess the appropriateness of an opioid prescription by understanding the continuum of risk and benefit.

Assessing Risk for Harms of Opioid Therapy

Inadequate evidence is available to support the predictive value of any screening measure for opioid risk; therefore, the work group does not recommend any particular screening tool. Instead, they recommend that physicians undertake a comprehensive systematic clinical evaluation of potential risk factors prior to initiating opioid therapy. The table "Risk Factors for Adverse Outcomes of Opioid Therapy and Opioid Misuse" in the original guideline document outlines factors that have been associated in published studies with risk of opioid misuse or adverse opioid outcomes.

If opioids are required and the patient is at a very high risk of opioid complications, hospitalization or other close monitoring may be required.

Saying "No"

Many clinicians fear or have experience with irate patients who are seeking relief and/or seeking drugs. It is important to have self-awareness about the issues involved and personally identify colleagues to gain insight, advice and support when dealing with these patients.

Developing personal scripting and also having discussions with colleagues about how best to approach and care for these patients may be

supportive and help develop confidence in managing a potentially tense discussion.

- Do not negotiate with intoxicated patients or patients in withdrawal.
- Before saying "no" or evincing resistance, gather information using a neutral tone.
- Be self-aware of your own discomfort. If feeling emotionally pressured (patient anger or pleas for sympathy), separate your feelings from the medical facts you are observing and standard of care you practice. Do not respond to emotion with emotion. And do not prescribe emotionally.
- Before you say "no," ask the patient about his or her function, life stress, pill use behaviors and other substance use. Then use the patient's own reports, if appropriate, to reframe opioids from "pain killer" to function restorer; remind the patient that pain is amplified by life stress.
- Suggest to the patient that the pain may resolve on its own without risking increased tolerance and other adverse events of opioids. Recommend waiting one week or more before a dose change.
- Make sure the patient is well-informed about what he or she is asking. Clinicians may erroneously assume patients know more than they do or feel manipulated by them. Yet, often patients approach this naively and need education. Explain to them your thinking, assuming they are being sincere.
- If you are uncertain about the medical/pharmacologic issues, step out and confer with a colleague or a team. Before you proceed, admit you need advice and you would like to review the case with an expert. Consider referral to a specialist.
- Focus on what therapy you are providing and how it will help the patient's pain.
- Remind the patient of the hospital or clinic policy, if he or she is requesting an exception; legal issues if relevant; and health issues, side effects and contraindications, including safety (falls, driving, etc).
- Maintain a sympathetic approach. Listen unrushed. Work toward building a relationship. Express that you are not "denying them" to be punitive but that you think the medication request is actually ill-advised. Offer close follow-up and reevaluations.

Clinicians and organizations are encouraged to develop scripting for patients who have a history of substance use and/or for whom opioid therapy is not appropriate. (See Appendix B, "Scripting Support for Saying No to a Patient and an Opioid Prescription," in the original guideline document.)

Refer to the original guideline for information on patient education and shared decision-making.

14. Appropriate Therapy and/or Referral
    - Treat with other analgesics or NSAIDs, physical, psychological, interventional or other appropriate non-opioid therapies.
      Non-opioid analgesics for pain and/or therapies that would support pain relief, improved function or healing should be the first consideration. Some types of pain would be better managed with alternative medications, such as gabapentin for neuropathy or calcitonin for bone pain associated with osteoporosis. However, NSAIDs and other anti-inflammatories are not without their limitations and side effects. For some conditions, they may prevent healing and should be prescribed judiciously *[Low Quality Evidence]*. Provide risks and benefits of all options for the patient to guide discussion and support shared decision-making. Additional information on the "Shared Decision-Making Model" can be found on the ICSI Web site .

      Identification of appropriate treatment must also include evaluation of activities of daily living (ADLs), work situation and psychosocial needs. If available, include in the discussion supportive family members and/or caregivers as identified by the patient. Document treatment recommendations in the patient's plan of care, and provide this information to the clinician who will be providing follow-up care.

      For additional information on evidence-based treatment modalities for pain, see the NGC summary of the ICSI guideline Assessment and management of chronic pain.

    - Reassure and provide patient education, including expected duration of pain episode and warning signs that would require immediate medical attention.
      With many acute pain situations, the clinician can help the patient anticipate the endpoint for pain. For instance, viral infections have an endpoint, and a broken bone has a point where the pain should be subsiding. It is important to share the information so the patient knows what to expect.

      If the pain does not appropriately improve in the expected time frame, patients should follow up with their primary care physician for reassessment and a referral to a behavioral health or pain specialist as needed.

15. Prescription of Opioids
    - Avoid prescribing more than three days' supply or 20 pills of low-dose, short-acting opioids, unless circumstances clearly warrant additional opioid therapy. (Tramadol is an atypical opioid and should be managed appropriately.)

A recent study demonstrated that many patients who fill their opioid prescriptions may not use them as prescribed, and may have leftover pills or save them for a later pain episode, potentially increasing the possibility of diversion *[Low Quality Evidence]*.

Tramadol is not considered a controlled substance in the U.S., and while it is efficacious for fibromyalgia, it has some potential for abuse. Clinicians should prescribe appropriately and follow-up with the patient to verify effectiveness and correct usage.

- Never prescribe long-acting/extended-release opioid preparations for acute episodes of pain.
- Caution using opioids in the elderly.
- Primary care should follow up with patient within three to five days.
  The prescribing clinician should schedule and/or communicate to the patient and his or her primary care clinic the need to follow up within three to five days to assess pain management and appropriate use of pain medication. Depending on the patient condition, this follow-up may be done telephonically by a care manager or other primary care team member, as well as face to face.
- Shared decision-making; patient must be educated on opioid risks and benefits to make an informed decision.
  Patients may opt for an alternative pain medication or treatment after being made aware of the potential side effects, driving and work limitations, and disposal and diversion considerations. Patients also benefit from reassurance and discussion about the anticipated duration of pain.
- Review side effects.
  Discuss all potential side effects with the patient, including discussion of potential constipation side effects and ways to manage.
- Review safe driving, work, storage and disposal.
  See Annotation #12, "Complete the ABCDPQRS Opioid Risk Assessment."
- Maximize appropriate non-opioid therapies.
  Consider other treatments and therapies that may provide support pain management. Inform the patient of expected results and outcomes from these options.

Definitions:

Following a review of several evidence rating and recommendation writing systems, Institute for Clinical System Improvement (ICSI) has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Crosswalk between ICSI Evidence Grading System and GRADE

ICSI GRADE System	Previous ICSI System	
High, if no limitation	Class A:	Randomized, controlled trial
Low	Class B:	[observational]
		Cohort study
	Class C:	[observational]
		Non-randomized trial with concurrent or historical controls
Low		Case-control study
Low		Population-based descriptive study
*Low		Study of sensitivity and specificity of a diagnostic test
*Following individual study review, may be elevated to Moderate or High depending upon study design		
	Class D:	[observational]

ICSI GRADE System	Previous ICSI System	Cross-sectional study
Low		Case series
		Case report
Meta-analysis	Class M:	Meta-analysis
Systematic Review		Systematic review
Decision Analysis		Decision analysis
Cost-Effectiveness Analysis		Cost-effectiveness analysis
Low	Class R:	Consensus statement
Low		Consensus report
Low		Narrative review
Guideline	Class R:	Guideline
Low	Class X:	Medical opinion

Evidence Definitions

High Quality Evidence = Further research is very unlikely to change confidence in the estimate of effect.

Moderate Quality Evidence = Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Low Quality Evidence = Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a Reference throughout the document.

Clinical Algorithm(s)

The following detailed and annotated clinical algorithms are provided in the original guideline document :

- Acute Pain Assessment and Opioid Prescribing Protocol (Main Algorithm)
- Risk Assessment and Treatment

Scope

Disease/Condition(s)

Acute pain, including:

- Anticipated postoperative pain
- Tooth pain

Guideline Category

Diagnosis

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Dentistry

Emergency Medicine

Family Practice

Geriatrics

Internal Medicine

Neurology

Pharmacology

Psychology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dentists

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Pharmacists

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Substance Use Disorders Treatment Providers

Guideline Objective(s)

- To decrease the rate of opioid prescriptions for adults 18 years and older with diagnoses that do not warrant opioids (diagnoses may

include fibromyalgia, headache, sore throat, uncomplicated neck and back pain, uncomplicated musculoskeletal pain)
- To increase the number of opioid prescriptions for adults 18 years and older that have documented review of prescription monitoring program in the electronic health record (EHR)
- To decrease the rate of adult patients 18 years and older with opioid prescriptions for non-traumatic tooth pain
- To increase the rate of adult patients 18 years and older who receive information on risks and benefits of opioid prescription

Target Population

Adult (18 years and older) non-cancer, acute or subacute pain outpatient, including:

- The adult, non-cancer, acute and subacute pain outpatient
- The adult, non-cancer chronic pain patient experiencing unrelated acute pain
- The adult, non-cancer patient with acute exacerbation of chronic pain

Note: The assessment of pain and management of patients with active cancer and/or receiving palliative or hospice care, including non-cancer diagnoses, are not addressed within the context of this protocol and are out of the scope and target population.

Interventions and Practices Considered

1. Brief pain assessment in emergency setting
2. Comprehensive pain assessment
    - Medical history, including past and current opioid use
    - Appropriate diagnostics, including use of numeric pain scales
3. Symptomatic management of non-traumatic tooth pain
4. Appropriate therapy and/or referral
    - Non-opioid analgesics or non-steroidal anti-inflammatory drugs (NSAIDs)
    - Psychological or interventional therapy
5. Patient education
6. Opioid risk assessment (ABCDPQRS), including:
    - Alcohol use
    - Benzodiazepines and other drug use
    - Clearance and metabolism of the drug
    - Delirium, dementia and falls risk
    - Psychiatric comorbidities
    - Respiratory insufficiency and sleep apnea
7. Prescription of opioids, including review of side effects

Major Outcomes Considered

- Sensitivity and specificity of screening tools
- Appropriateness of using opioids
- Adverse effects of opioids

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A consistent and defined process is used for literature search and review for the development and revision of Institute for Clinical Systems Improvement (ICSI) protocols. The literature search was divided into two stages to identify systematic reviews (stage I) and randomized controlled trials, meta-analyses and other literature (stage II). Literature search terms used in PubMed for this revision are related to opioids: prescribing, acute pain management, misuse, abuse, tolerance, addiction, overdosing, cost, diversion, pain specialists and risk assessments; they include literature from May 2010 through May 2013.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Following a review of several evidence rating and recommendation writing systems, Institute for Clinical System Improvement (ICSI) has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Crosswalk between ICSI Evidence Grading System and GRADE

ICSI GRADE System	Previous ICSI System	
High, if no limitation	Class A:	Randomized, controlled trial
Low	Class B:	[observational]
		Cohort study
	Class C:	[observational]
		Non-randomized trial with concurrent or historical controls
Low		Case-control study
Low		Population-based descriptive study
*Low		Study of sensitivity and specificity of a diagnostic test
*Following individual study review, may be elevated to Moderate or High depending upon study design		
	Class D:	[observational]
Low		Cross-sectional study
		Case series
		Case report
Meta-analysis	Class M:	Meta-analysis
Systematic Review		Systematic review

ICSI GRADE System	Previous ICSI System	
Decision Analysis		Decision analysis
Cost-Effectiveness Analysis		Cost-effectiveness analysis
Low	Class R:	Consensus statement
Low		Consensus report
Low		Narrative review
Guideline	Class R:	Guideline
Low	Class X:	Medical opinion

Evidence Definitions

High Quality Evidence = Further research is very unlikely to change confidence in the estimate of effect.

Moderate Quality Evidence = Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Low Quality Evidence = Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a Reference throughout the document.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Document Development

A work group consisting of 6 to 12 members that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, and an Institute for Clinical Systems Improvement (ICSI) staff facilitator develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 work group members may be recruited from medical groups, hospitals or other organizations that are not members of ICSI.

The work group will meet for 3 to 4 three-hour meetings to develop the protocol. Under the coordination of the ICSI staff facilitator, the work group develops the algorithm and writes the annotations, citing literature where appropriate.

Once the final draft copy of the protocol is developed, the document is sent to the ICSI members for critical review.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Review and Comment

The purpose of the review and comment process is to provide an opportunity for the clinicians in the member organizations to review the science behind the recommendations and focus on the content of the protocol. Review and comment also provides an opportunity for clinicians in each organization to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the protocol.

All member organizations are encouraged to provide feedback on protocols; however, responding to review and comment is not a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

Document Approval

Each protocol is approved by the appropriate steering committee. There is a steering committee for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each protocol based on:

- Member comments have been addressed reasonably.
- There is sufficient reason to expect that members will use the protocol with minor modifications or adaptations.
- Within the knowledge of the reviewer, the recommendations in the protocol are consistent with other protocols, regulatory and safety requirements, or recognized authorities.
- When evidence for a particular step in the protocol has not been established, the work group identifies consensus statements that were developed based on community standard of practice and work group expert opinion.
- Either a review and comment by members has been carried out, or within the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of review is not needed.

Once the document has been approved, it is posted on the ICSI Web site and released to members for use.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is classified and/or graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate assessment of acute pain and prescription of opioids
- Support for both the patient and the clinician, highlighting these specific values:
  - Patient safety
  - Supportive pain management
  - Community safety and population health
  - Prevention of inappropriate or overutilization of opioids
  - Patient information and shared decision-making

Potential Harms

- Non-steroidal anti-inflammatory drugs (NSAIDs) and other anti-inflammatories are not without their limitations and side effects. For some conditions, they may prevent healing and should be prescribed judiciously.
- Recent buprenorphine or naltrexone use will block the analgesic effects of opioids and could precipitate opioid withdrawal.
- Opioid use disorder (i.e., heroin or pharmaceutical opioid addiction) makes management of pain with opioids highly problematic. Additional opioid prescriptions should be avoided in patients actively addicted to opioids, if at all possible.

See Annotations 10 and 12 in the "Major Recommendations" field for additional information on adverse effects of opioids.

Contraindications

Contraindications

- Alcohol and benzodiazepine (BZD) used concurrently with opioids increase the risk of oversedation, overdose and trauma.
- For patients with impaired liver function, consider lowering the dose of acetaminophen or, preferably, avoiding the use of acetaminophen/opioid combination medication altogether.
- Patients on acute dosing of opioids are at an increased risk from falls and other accidental trauma. This is particularly so for geriatric patients. Opioids should be used cautiously for patients with past falls or at an increased risk of fracture. Some guidelines suggest prescribing half the normal initial dose when treating the elderly. Other central nervous system (CNS) depressants such as anticholinergic medications, alpha adrenergic blockers and benzodiazepines will compound the risk of falls and fractures in patients on opioids. Opioids can precipitate delirium in some patients. Those with significant risk factors for opioid-induced delirium include the elderly; patients with cognitive impairments, polypharmacy, advanced liver or kidney disease; and patients with prior episodes of delirium precipitated by opioids.
- Patients on acute dosing of opioids are at an increased risk from falls and other accidental trauma. This is particularly so for geriatric patients.

See Annotation 12 in the "Major Recommendations" field for additional information on contraindications to opioids.

Qualifying Statements

Qualifying Statements

- The information contained in this Institute for Clinical Systems Improvement (ICSI) Health Care Protocol is intended primarily for health professionals and other expert audiences.
- This ICSI Health Care Protocol should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Protocol and applying it in their individual case.
- This ICSI Health Care Protocol is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

- Patients often seek dental care in medical facilities because they are more accessible and may not be able to refuse treatment. The Minnesota Dental Association (MDA) recognizes that a clinician should always use clinical judgment to provide the most appropriate and comprehensive care for the individual patient. The work group also recognizes the MDA for the development of this position statement and acknowledges that there are situations that represent challenges to care, including dental insurance coverage and dental provider availability. Health care delivery systems and dental organizations need to collaborate and develop standards of care and processes that support the clinician and the patient when managing tooth pain.

Implementation of the Guideline

Description of Implementation Strategy

Description of Implementation Strategy

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Implementation Recommendation Highlights

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

- Communicate a clear and consistent opioid usage message for clinicians that clarifies the benefits and risks for patients.
- Create a checklist from the ABCDPQRS Opioid Risk Assessment in the electronic health record.
- Create educational materials for patients and consumers to clarify the benefits and risks of opioid use.
- Use health care medical records and a prescription monitoring program (PMP) to identify a patient's opioid history.
- Document opioid prescriptions, along with any additional risk factors or comorbidities, in the patient electronic health record.

Implementation Tools

Chart Documentation/Checklists/Forms

Clinical Algorithm

Quality Measures

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Thorson D, Biewen P, Bonte B, Epstein H, Haake B, Hansen C, Hooten M, Hora J, Johnson C, Keeling F, Kokayeff A, Krebs E, Myers C, Nelson B, Noonan MP, Reznikoff C, Thiel M, Trujillo A, Van Pelt S, Wainio J. Acute pain assessment and opioid prescribing protocol. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2014 Jan. 44 p. [76 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Jan

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

The Institute for Clinical Systems Improvement (ICSI) is comprised of 50+ medical group and hospital members representing 9,000 physicians in Minnesota and surrounding areas, and is sponsored by five nonprofit health plans. For a list of sponsors and participating organizations, see the ICSI Web site.

Source(s) of Funding

- The Institute for Clinical Systems Improvement (ICSI) provided the funding for this guideline. The annual dues of the member medical groups and sponsoring health plans fund ICSI's work. Individuals on the work group are not paid by ICSI, but are supported by their medical group for this work.
- ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups, and sponsoring health plans review and provide feedback, but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Guideline Committee

Committee on Evidence-Based Practice

Composition of Group That Authored the Guideline

Work Group Members: David Thorson, MD (*Work Group Leader*) (Entira Family Clinics) (Sports Medicine); Justin Hora, PharmD (Allina Medical Clinic) (Pharmacy); Chris Johnson, MD (Emergency Physicians, PA) (Emergency Medicine); Susan Van Pelt, MD (Emergency Physicians, PA) (Emergency Medicine); Faris Keeling, MD (Essentia Health) (Psychiatry); Anne Kokayeff, MD (Fairview Health Services) (Pain Medicine); Bret Haake, MD (HealthPartners Medical Group and Regions Hospital) (Neurology); Mary Pat Noonan, PhD, ABPP (HealthPartners Medical Group and Regions Hospital) (Clinical Psychology); Charles Reznikoff, MD (Hennepin County Medical Center) (Internist, Addiction); Brian Bonte, DO (Hutchinson Health) (Family Medicine); Marsha Thiel, RN, MA (MAPS Medical Pain Clinic) (Pain Medicine); Anne Trujillo, RN, CNP (MAPS Medical Pain Clinic) (Pain Medicine); Michael Hooten, MD (Mayo Clinic) (Anesthesiology); Erin Krebs, MD, MPH (Minneapolis VA Health Care System) (Internal Medicine); John Wainio, DDS (Minnesota Dental Association) (General Dentistry); Brian Nelson, MD (Physicians Neck and Back Clinic) (Orthopedics); Paul Biewen, MD (Twin City Orthopedics) (Physical Medicine and Rehabilitation); Howard Epstein, MD (Institute for Clinical Systems Improvement [ICSI]) (Chief Health Systems Officer); Carmen Hansen, RN, BSN (ICSI) (Project Manager); Cassie Myers (ICSI) (Clinical Systems Improvement Facilitator)

Financial Disclosures/Conflicts of Interest

The Institute for Clinical Systems Improvement (ICSI) has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI protocols and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report Clinical Practice Protocols We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at the ICSI Web site .

Disclosure of Potential Conflicts of Interest

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Guideline Related Activities: ICSI Adult and Subacute Low Back Pain
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Financial/Non-Financial Conflicts of Interest: None

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Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Financial/Non-Financial Conflicts of Interest: None

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Financial/Non-Financial Conflicts of Interest: None

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Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Research Grants: None
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Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Availability of Companion Documents

The appendices of the original guideline document contains a sample opioid prescription patient agreement and criteria for substance use disorders.

A podcast is available from the Institute for Clinical Systems Improvement Web site.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 21, 2014. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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